



July 27, 2004

Alimta Receives Positive Endorsement for Lung Cancer Approval from FDA Advisory Committee

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Unanimous Endorsement for Accelerated Approval in Second-Line Non-Small Cell Lung Cancer

Eli Lilly and Company announced today that the Oncologic Drugs Advisory Committee (ODAC) of the U.S. Food and Drug Administration positively endorsed Alimta[®] (pemetrexed), an antifolate, for accelerated approval in the second-line treatment of non-small cell lung cancer.

"The committee's unanimous recommendation is a major step forward for patients being treated for non-small cell lung cancer in the second-line setting," said Paolo Paoletti, M.D., vice president of oncology clinical research at Lilly. "Study data show that Alimta's effectiveness is comparable to Taxotere, is conveniently administered and is better tolerated."

The ODAC recommendation supports a possible FDA approval of Alimta as a single-agent therapy for patients with locally advanced or metastatic non-small cell lung cancer after receiving prior chemotherapy. The committee based its opinion upon one of the largest Phase III studies to date in the second-line setting in which Alimta was compared head-to-head to Taxotere[®] (docetaxel).

The Phase III study showed:

- Alimta demonstrated a survival benefit similar to Taxotere (8.3 months median survival vs. 7.9 months median survival, favoring Alimta).
- Alimta had a response rate (tumor shrinkage) of 9.1 percent compared to a response rate of 8.8 percent for Taxotere.
- Alimta and Taxotere had similar progression-free survival rates of 2.9 months. Progression-free survival represents the number of months that a patient's disease remains in remission following treatment without the disease getting any worse.
- Compared to Taxotere, patients who received Alimta experienced less Grade 3 or 4 neutropenia (neutropenia is a decrease in infection-fighting white blood cell counts), less neutropenia with fever, less diarrhea, fewer hospitalizations due to adverse events and less hair loss. Patients treated with Alimta did experience higher rates of Grade 3 or 4 Alanine Transaminase (ALT), a laboratory measurement of liver function.

Paul Bunn, M.D., Director of the University of Colorado Cancer Center said, "I agree that Alimta should be available for patients with lung cancer who are being treated in the second-line setting. Based on its similar efficacy and superior side effect profile, Alimta is a better alternative than the current standard of care, Taxotere."

If approved by the FDA for treatment of second-line non-small cell lung cancer, Alimta would have two indications in the U.S. In February 2004, the FDA approved Alimta, in combination with cisplatin, a commonly-used chemotherapy agent, for use in the treatment of malignant pleural mesothelioma, a devastating cancer often associated with asbestos exposure.

In June 2004, the European Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for a dual indication for Alimta. The CHMP's recommended approval of Alimta as a single-agent for patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy and in combination with cisplatin for the treatment of malignant pleural mesothelioma. This opinion for dual indication represents a regulatory first for Lilly.

Alimta, in combination with cisplatin, is also approved in Argentina, Canada, Israel and Australia for the treatment of malignant pleural mesothelioma. In Australia, Alimta is also approved as a single-agent for the treatment of second-line non-small cell lung cancer.

About Lung Cancer

Non-small cell lung cancer is a disease in which malignant cancer cells form in the tissues of the lung. According to the American Cancer Society, non-small cell lung cancer is the leading cause of cancer-related death in both men and women.

More than 174,000 people are diagnosed with lung cancer in the United States each year. In the U.S., approximately 80 percent of patients diagnosed with lung cancer are identified with non-small cell lung cancer. Currently somewhere between 60 - 70 percent of all patients who are diagnosed with lung cancer will receive first-line treatment (about 85,000 - 100,000 patients a year); and half of those treated in the first-line will receive second-line therapy (about 40,000 - 50,000 patients per year).

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs.

Lilly Oncology, a division of Eli Lilly and Company, is a leader in cancer research and treatment, with therapies that are considered the standard of care in a number of difficult-to-treat tumor types and a vibrant research platform driving therapeutic innovation.

Alimta® (pemetrexed , Lilly)

Taxotere® (docetaxel, Aventis)